July 2006

Arizona State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Universal Medication Form, (Medication Reconciliation)

Arizona hospitals are increasing efforts to educate patients and families about the importance of maintaining their own up-to-date medication and allergy lists. Hospitals realize they can best treat patients if they have reliable information on which to base their treatment decisions. Someday, hospitals hope to have the information stored on so called "smart cards," which are currently used in France. In the meantime, a paper-based low-tech system is being promoted to provide for medication reconciliation. The goal of reconciliation programs is to allow doctors and hospitals to coordinate therapy with the treatment a patient is receiving before a hospital admission with treatments while in the hospital and upon discharge from the hospital to a community pharmacy. The Arizona Hospital and Healthcare Association provides a sample form and directions for maintaining the form at the link www.themedform.com.

Board Member Reappointment

Arizona State Board of Pharmacy member Dennis K. McAllister, affectionately known by his former students from Midwestern University as "Professor McAllister," has been reappointed to the Board by Governor Janet Napolitano. On January 16, 2006, his term on the Board was extended to January 16, 2011. The reappointment was anticipated and well received by the current Board members, who are predominately new members. His years of experience on the Board will prove to be a valuable resource to the new Board members and staff. After a review of the records at the Board office, it was determined that Mr McAllister will have served the third longest tenure of any Board member in the 103 years of the Board. Only Ferdy Sant from Yuma (1959-1986) and Danny Jacob from Tucson (1984-2000) have served longer terms. After a review of Board meeting minutes, it was also determined that Mr McAllister has never missed a scheduled Board meeting, despite his travels from Sierra Vista, AZ, in the early years of his tenure and a demanding travel schedule imposed upon him as a member of the National Association of Boards of Pharmacy® (NABP®) Executive Committee, including a term as NABP president, which ended in May 2006. Mr McAllister is now serving a one year term as chairperson of the NABP Executive Committee.

It IsTime To Update Changes of Address and/or Employment as Required

In anticipation of the October 2006 credential renewal cycle, which will begin near the middle of September 2006, please be reminded that all licensees and permittees shall keep their address and/or employment current at the Board offices. Not only is this a statutory requirement, but it may save quite a bit more time and money than a late fee as this is your address for all Board notices. The notice of changes must be in writing, and reporting by fax, e-mail, or the Board Web site is acceptable. The link to the form on the Board Web site is under the section "Contact Us" at the link: www.eomniform.com/servlet/FillForm/hwand/CHANGEADDRESS.

Frequent Failures To Comply on Board Inspections

The Board instructed staff to report that the three most common non-compliance issues noted by the compliance officers are:

1. Controlled Substance (CS) Shortages/Overages (Recordkeeping).
2. Failure to document patient medical conditions/allergies.
3. Failure to have Technician Training statements signed and on file in the pharmacy, detailing job description, understanding of policy and procedures and Board rules.

Disciplinary Actions – Board of Pharmacy (Actions Since April 2006 Newsletter)

Notice: Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (Board).

Thomas Bannister (RPh #08040) – 90-Day Probation. Effective March 15, 2006.

David Hall (RPh #13049) – Revoked. Effective May 24, 2006.

Sharon Huie (RPh #06619) – 90-Day Probation. Effective March 15, 2006.

Dennis Lambert (RPh #06623) – 90-Day Probation. Effective March 15, 2006.

John Markus (RPh #10719) – One-Year Suspension. Effective May 24, 2006.

Richard Pillon (RPh #06697) – Six-Month Probation. Effective May 24, 2006.

Gary Sorensen (RPh #13246) – Six-Month to One-Year Suspension, five year Pharmacists Assisting Pharmacists in Arizona (PAPA) contract, Effective March 3, 2006.

Yvonne Trujillo (Tech #00181) – Revoked. Effective May 24, 2006.

Michael Yoha (RPh #13936) – Six-Month to One-Year Suspension, five year PAPA contract, Effective March 17, 2006.

Alana Zinkie (Tech #07250) – Revoked. Effective May 24, 2006.

Marvin Fein (RPh # 14591) – Revoked. Effective May 25, 2006.

Christine Bona (Tech # 5242) – Revoked. Effective May 25, 2006.

Disciplinary Actions – Other Health Care Practitioner Boards

Gary W. Ehlers, PA (#1402) – Decree of Censure Amend, Prescribing

Continued on page 4

Generic Substitution Issues

This is a reminder to pharmacists regarding the legal generic substitution of certain drug products. Recent practices by pharmaceutical manufacturers involving the reformulation of drugs into alternative dosage forms (eg, tablets to capsules) seem to have caused some confusion.

Generic substitution is the act of dispensing a different brand or unbranded drug product than the one prescribed. Generic substitution is only allowable when the substituted product is therapeutically equivalent to the prescribed innovator product. Generic drug manufacturers must provide evidence to Food and Drug Administration (FDA) of therapeutic equivalence, which means that both products are pharmaceutically equivalent (eg, have the same active ingredients in the same dosage form and strength, and use the same route of administration) and bioequivalent (eg, have more or less the same rate and extent of absorption). Therapeutically equivalent drugs are expected to produce the same clinical benefits when administered for the conditions approved in the product labeling.

FDA assigns two-letter therapeutic equivalence codes to generic products when the products meet both the aforementioned requirements, are approved as safe and effective, are adequately labeled, and are manufactured in compliance with current Good Manufacturing Practice regulations. The primary reference guide for pharmacists on therapeutic equivalence is FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book." Drug products determined to be therapeutically equivalent to innovator drugs are assigned an "A" for the initial letter of their therapeutic equivalence code. The second letter provides additional information regarding the product: products rated AA, AN, AO, AP, or AT are those with no known or suspected bioequivalence problems (rating depends on dosage form). An AB rated product indicates that actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence. In contrast, drugs assigned a "B" for the initial letter are not considered therapeutically equivalent because bioequivalence problems have not been resolved to the satisfaction of FDA.

A recent example of improper substitution has been brought to the attention of several boards of pharmacy by Acorda Therapeutics, the maker of Zanaflex® tablets, who recently released Zanaflex Capsules™ (tizanidine hydrochloride). Although the active ingredient in Zanaflex Capsules is the same as the active ingredient in Zanaflex tablets and generic tizanidine tablets, their formulations are different. For this reason, FDA has deemed there to be no therapeutic equivalent to Zanaflex Capsules and has not assigned a therapeutic equivalence code.

A similar situation existed in 1995 when the manufacturer of Sandimmune® (cyclosporine) capsules and oral solution, Sandoz, (now Novartis), came out with NEORAL® (cyclosporine) capsules and oral solution for microemulsion. Due to differences in bioavailability, Sandimmune and Neoral, and their accompanying generic versions, were not, and still are not, rated as substitutable.

It must be emphasized that generic substitution mandates are found in individual state laws and regulations. In states where generic substitution is allowed only for "Orange Book" A-rated products, pharmacists may not substitute a generic product for a non-A-rated product. Some states may have developed their own generic substitution lists or formularies. Pharmacists are encouraged to review the laws and regulations in their states to determine the appropriate legal methods by which to perform generic substitution.

Preventing Errors Linked to Name Confusion

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

The Institute for Safe Medication Practices (ISMP) regularly hears about confusion between products with similar names. One such pair is OMACOR (omega-3-acid ethyl esters) and AMICAR (aminocaproic acid) an antifibrinolytic. Omacor is indicated as an adjunct to diet to reduce very high triglyceride levels (500 mg/dL or more) in adult patients. The drug is also being studied as adjuvant therapy for the prevention of further heart attacks in patients who have survived at least one. A pharmacist reported an error in which a telephone order for Omacor 1 gram BID was interpreted and dispensed as Amicar 1 gram BID. Counseling was not provided, but fortunately the patient read the drug information sheet for Amicar before taking any medication and called the pharmacy stating that he was expecting a medication to reduce his triglyceride levels.

While this case illustrates why manufacturers should review and test new trademarks for error potential before the product reaches the market, there are some things that practitioners can do to help prevent errors with products that have look-alike or sound-alike names.

- Look for the possibility of name confusion before a product is used. Use the concepts of failure mode and effects analysis (FMEA) to assess the potential for error with new medications that will be prescribed or added to your inventory. If the potential for confusion with other products is identified, take the steps listed below to help avoid errors.
- Prescriptions should clearly specify the drug name, dosage form, strength, complete directions, as well as its indication. Most products with look- or sound-alike names are used for different purposes. If the indication is not available, pharmacists and nurses should verify the purpose of the medication with the patient, caregiver, or physician before it is dispensed or administered.
- Reduce the potential for confusion with name pairs known to be problematic by including both the brand and generic name on prescriptions, computer order entry screens, prescription labels, and MARs.

- When accepting verbal or telephone orders, require staff to write down the order and then perform a read back (or even spell back) of the medication name, strength, dose, and frequency of administration for verification.
- Change the appearance of look-alike product names on computer screens, pharmacy product labels, and MARs by emphasizing, through bold face, color, and/or tall man letters, the parts of the names that are different (eg, hydrOXYzine, hydrALAzine).
- Pharmacists should work under good lighting and use magnifying lenses and copyholders (keep prescriptions at eye level during transcription) to improve the likelihood of proper interpretation of look-alike product names.
- Install computerized reminders for the most commonly confused name pairs at your site so that an alert is generated when entering prescriptions for either drug. If possible, make the reminder auditory as well as visual.
- Store commonly confused products in different locations. Avoid storing both products in a "fast-mover area." Use a shelf sticker to help find relocated products.
- Affix "name alert" stickers to areas where look- or sound-alike products are stored (available from pharmacy label manufacturers) or to the actual product containers.
- Employ at least two independent checks in the dispensing process (one person interprets and enters the prescription into the computer and another compares the printed label with the original prescription as well as the manufacturer's product).
- Open the prescription bottle or package in front of the patient to confirm the expected appearance of the medication and review the indication. Caution patients about error potential when taking a product that has a look- or sound-alike counterpart. Encourage patients to ask questions if the appearance of their medication changes. Take time to fully investigate any patient concerns.
- Encourage reporting of errors and potentially hazardous conditions with look- and sound-alike names to the ISMP-USP Medication Errors Reporting Program and use the information to establish priorities, as listed above, for error reduction. Maintain an awareness of problematic product names and error prevention recommendations provided by ISMP (www.ismp.org), FDA (www.fda.gov), and USP (www.usp.org).

If you are interested in learning what look-alike and sound-alike name pairs have been published in the ISMP Medication Safety Alert!®, a free list is available at www.ismp.org/Tools/confuseddrugnames.pdf.

Combat Methamphetamine Epidemic Act Phasing In

This year, new requirements of the federal Combat Methamphetamine Epidemic Act passed by Congress for the sale of all single and multi-ingredient pseudoephedrine and ephedrine-containing products will become effective. The new law places non-prescription ephedrine, pseudoephedrine, and phenylpropanolamine in a new Controlled Substances Act category of "scheduled listed chemical products." Drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine are subject to sales restrictions, storage requirements, and record keeping requirements.

A 3.6-grams-per-day base product sales limit, 9-grams-per-30-days base product purchase limit, a blister package requirement, and mail-order restrictions went into effect on April 8, 2006, for all sellers of these products. All other provisions of the law require compliance by September 30, 2006. If a state has more stringent requirements, the stronger requirements remain in place. A summary of this Act's requirements can be found on the United States Drug Enforcement Administration's (DEA) Web site at www.deadiversion.usdoj.gov/meth/cma2005.htm.

Explanation of DEA Regulations on Partial Refilling of Prescriptions

Pharmacists often question the DEA rule regarding the partial refilling of Schedule III, IV, and V prescriptions as stated in Section 1306.23 of the Code of Federal Regulations. Confusion lies in whether or not a partial fill or refill is considered one fill or refill, or if the prescription can be dispensed any number of times until the total quantity prescribed is met or six months has passed. According to DEA's interpretation, as long as the total quantity dispensed meets the total quantity prescribed with the refills and they are dispensed within the six-month period the number of times it is refilled is irrelevant. The DEA rule is printed below:

Section 1306.23 Partial Filling of Prescriptions.

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that:

(a) Each partial filling is recorded in the same manner as a refilling,
(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and
(c) No dispensing occurs after 6 months after the date on which the prescription was issued.

[21 CFR 1306.23]

Electronic Version of DEA Form 106 Now Available

DEA has announced that a secure, electronic version of the DEA Form 106 (Report of Theft or Loss of Controlled Substances) is now available to DEA registrants. The electronic form may now be completed online through a secure connection and submitted via the Internet to DEA Headquarters. Copies of the letter from DEA and the 2005 Final Rule were published in the *Federal Register*. The new interactive form is located at the Diversion Control Program's Web site and may be accessed at www.DEAdiversion.usdoj.gov.

Patients Rely on Pharmacists' Recommendations

Patients consider their pharmacists a trusted source for medication recommendations, as evidenced by the result of a poll recently conducted by the American Pharmacists Association (APhA). APhA polled 3,000 community pharmacists and found that pharmacists were asked about over-the-counter (OTC) products an average of 32 times each week. Of those pharmacists surveyed, 55% said they spend three to five minutes with each patient who asks about an OTC. And patients are listening, for during this consultation time, according to the survey, 81% of patients purchased OTC products recommended by the pharmacist.

The results of the poll was published in APhA's *Pharmacy Today*. Other topics researched in the poll include recommendation habits of pharmacists in leading OTC therapeutic areas including treatments for allergies, adult cold symptoms, adult headache remedies, heartburn, pain relief, and tooth whitening products among others.

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Restriction Terminated. Effective March 1, 2006.

Leon Garza, PA (#2619) – One-Year Probation, Respondent Shall Not Prescribe Any Schedule II, III, IV, and V CS. Effective March 16, 2006.

Kathleen King, PA (#3195) – Surrender of License, Return of Wall Card and Certificate of Licensure. Effective March 2, 2005; Interim Consent, Respondent Shall Not Perform Health Care Tasks. Effective November, 18, 2005.

Sandra L. McCarthy, PA (#2116) – Letter of Reprimand. Effective February 8, 2006.

Troy A. McCarthy, PA (#2118) – Decree of Censure. No Action Taken. Effective February 7, 2006.

Karlyne F. Sanders, PA (#2498) – Revoked License; Return Certificate of Licensure. Effective March 2, 2006.

Abdol Rassol Arjmandfard, MD (#33227) – License Suspended From Practicing Allopathic Medicine Pending a Formal Hearing. Effective April 5, 2006.

Franklin H. Baroi, MD (#22605) – Decree of Censure and One-Year Probation with the Condition of 30 Hours Category I Continuing Medical Education (CME). Effective February 9, 2006.

Leandro F. Baterina, Jr, MD (#26528) – 10-Years Probation; Respondent Shall Not Practice Clinical Medicine in Arizona Until Completion of Plan A or B Outlined in the North Dakota Board Order. Effective October 13, 2005.

Michael S. Biscoe, MD (#20915) – License Inactive with Cause. Effective February 14, 2006.

Charles Bollmann, MD (#6020) – Letter of Reprimand with the Condition of 20 Hours Category I CME. Effective February 9, 2006.

Mirjana R. Curtis, MD (#14763) – Surrender of License. Effective December 14, 2005.

Stephen Flynn, MD (#3351) – License Suspended From Practicing Allopathic Medicine Pending a Formal Hearing. Effective January 30, 2006.

James D. Gadd, MD (#8696) – Three-Years Probation; Respondent Shall Not Practice Clinical Medicine or Direct Patient Care and is Prohibited from Prescribing Any Form of Treatment, Including Prescription Medicine. Effective February 9, 2006.

Thomas J. Grade, MD (#10424) – Restricted From Prescribing Schedule II or Schedule III Medications Pending a Formal Hearing. Effective December 8, 2005.

Mary Groves, MD (#30315) – License Suspended From Practicing Allopathic Medicine Pending a Formal Hearing. Effective October 18, 2005.

Robert D. Hunn, MD (#5215) – Letter of Reprimand. Effective February 9, 2006.

Bruce C. Hunter, MD (#20475) – License Suspended From Practicing Allopathic Medicine Pending a Formal Hearing. Effective January 30, 2006.

Walter John Jasin, MD (#10086) – Respondent Shall Not Practice Clinical Medicine or Direct Patient Care and is Prohibited from Prescribing Any Form of Treatment, Including Prescription Medicine. Effective January 27, 2006.

Stanford C. Lee, MD (#30685) – Letter of Reprimand. Effective April 6, 2006.

Gary L. Lowery, MD (#24907) – Surrender of License. Effective February 9, 2006.

Lance A. May, MD (#34267) – License Suspended From Practicing Allopathic Medicine Pending Formal Hearing. Effective February 22, 2006.

Alexander Christian Miles, MD (#31553) – Respondent Shall Not Practice Clinical Medicine or Direct Patient Care and is Prohibited from Prescribing Any Form of Treatment, Including Prescription Medicine. Effective January 9, 2006.

Howard L. Mitchell, MD (#30004) – Decree of Censure, One-Year Probation with the Condition of 20 Hours Category I Professional Acknowledgment for Continuing Education CME and 20 Hours of CME in Pain Management. Effective October 13, 2005; Effective February 10, 2006.

William E. Mora, MD (#13088) – Respondent Shall Not Practice Clinical Medicine or Direct Patient Care and is Prohibited from Prescribing Any Form of Treatment, Including Prescription Medicine. Effective February 17, 2006.

John C. Morgan, MD (#25871) – Respondent Shall Not Practice Clinical Medicine or Direct Patient Care and is Prohibited from Prescribing Any Form of Treatment, Including Prescription Medicine. Effective May 3, 2006.

Mark R. Mouritsen, MD (#28909) – Decree of Censure and Five-Years Probation, Respondent Shall Not Prescribe Schedule II CS for a Period of two Years. Effective October 13, 2005.

Mahendra Nath, MD (#10234) – Respondent Shall Not Practice Clinical Medicine or Direct Patient Care and is Prohibited From Prescribing Any Form of Treatment, Including Prescription Medicine. Effective December 16, 2005.

John T. O'Mailey, MD (#25388) – Respondent Shall Not Practice Clinical Medicine or Direct Patient Care and is Prohibited From Prescribing Any Form of Treatment, Including Prescription Medicine. Effective May 23, 2006.

David D. Parrish, MD (#26896) – Suspended with One-Year Probation. Effective December 12, 2005.

Lawrence E. Pritchard, MD (#19260) – Revoked License. Effective February 10, 2006.

Larry P. Putnam, MD (#9233) – Respondent Shall Not Practice Clinical Medicine or Direct Patient Care and is Prohibited from Prescribing Any Form of Treatment, Including Prescription Medicine. Effective April 24, 2006.

Richard J. Reid, MD (#19106) – Revoked License. Effective December 12, 2005.

Alan I. Richman, MD (#25503) – Surrender of License, Return of Wall Card and Certificate of Licensure. Effective February 9, 2006.

Lawrence C. Runke, MD (#8190) – Surrender of License, Return of Wall Card and Certificate of Licensure. Effective February 9, 2006.

Dale W. Struble, MD (#34790) – Respondent Shall Not Practice Clinical Medicine or Direct Patient Care and is Prohibited from Prescribing Any Form of Treatment, Including Prescription Medicine. Effective January 27, 2006.

Tammy L. Tadom, MD (#31547) – Revoked License. Effective February 9, 2006.

Scott R. Werner, MD (#17352) – Surrender of License, Return of Wall Card and Certificate of Licensure. Effective February 9, 2006.

Jerald D. White, MD (#5146) – Letter of Reprimand. Effective December 12, 2005.

Vernon J. Williams, MD (#19036) – Unrestricted License and Reinstatement. Effective August 24, 2005.

John C. Woods, MD (#19005) – Revoked License, Return of Wall Card and Certificate of Licensure. Effective February 9, 2006.

The *Arizona State Board of Pharmacy News* is published by the Arizona State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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